Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision[i]

Actives substances(s): Cannabidiol (Epidyolex)

Latest Decision number(s): 1) P/0234/2022

Corresponding PIP number(s): 1) EMEA-001964-PIP03-21

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

Please note that development of the medicinal product above in the following **condition(s)/indication(s)**:

Epilepsy with myoclonic-atonic seizures

☒ has been discontinued

for the following reason(s): (tick all that apply)

☐ (possible) lack of efficacy in adults

☐ (possible) lack of efficacy in children

☐ (possible) unsatisfactory safety profile in adults

☐ (possible) unsatisfactory safety profile in children

☐ commercial reasons (please specify:)

☐ manufacturing / quality problems

☐ other regulatory action (please specify:)

☒ other reason (please specify: recruitment challenges)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation:

EMEA-001964-PIP03-21 included one phase 3 clinical study: GWEP20238 (EMAS) "A randomized, double-blind, placebo-controlled, multisite, Phase 3 study to investigate the efficacy and safety of cannabidiol oral solution (GWP42003-P) in children and adolescents with epilepsy with myoclonic-atonic seizures".

The GWEP20238 trial was discontinued early due to challenges with recruitment, and no planned analyses occurred. The decision to discontinue the trial was not the result of safety concerns.

No conclusions regarding the efficacy and safety of GWP42003-P could be made from the limited data from trial GWEP20238. However, no new safety concerns were identified during the study

As a result, the Sponsor made a decision to discontinue further development of Epidyolex for the treatment of EMAS.

Date:	03 December 2025
Contact for inquiries from interested parties:	Medical Information
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[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.